Instead of suggesting that this Court ought to grant the Petition to resolve this question, Medtronic contends that the merits of the Petition ought to be ignored because the timing issue presents a "vehicle" problem. But under that logic, this particular question might never be resolved by this Court (if it so desired) because future cases in a similar posture could always be dismissed as presenting the same "vehicle" problem. In any event, the timing question should be a non-issue that ought not impact this Court's decision regarding the merits of this Petition, but if anything, it gives this Court another reason to review this case.

4. Finally, Medtronic's opposition attempts to distract the Court by contending that the underlying merits claims in this case have been previously resolved. That is simply incorrect and a desperate attempt to divert the Court away from the important and timely issues presented by this Petition. Specifically, Medtronic incorrectly asserts that the claims raised in this *qui tam* suit were previously rejected by the Sixth Circuit in *Kemp v. Medtronic, Inc.*, 231 F.3d 216 (6th Cir. 2000). (Opp. 2-3). *Kemp* was a product liability case brought by victims of Medtronic's defective Model 4004M pacemaker leads. The issue in *Kemp* was whether the victims' state law tort claims against Medtronic were preempted by § 360k of the Medical Device Amendments ("MDA") to the Federal Food, Drug and Cosmetics Act ("FDCA"). 21 U.S.C. § 360k(a).

The court held that when the FDA approved Medtronic's PMA supplement application for the Model 4004M leads, the information contained in that application and the FDA's approval became the *de jure* "specific federal requirements" for purposes of the preemption analysis. 231 F.3d at 228. The court concluded that neither the application nor the FDA approval required a particular platinum sputter coverage or thickness specification, and that therefore plaintiffs' state law

claims, which sought to impose a platinum sputter coverage and thickness requirement, were preempted.[4] *Id.* at 228-32.

The Sixth Circuit's decision in *Kemp* was purely procedural and made solely in the context of a preemption analysis. *Kemp's* only relevance to this case is that it confirmed the existence of evidence that Medtronic, in fact, had changed its platinum sputter design. *See id.* at 230 (noting that Medtronic "modified the design"). That fact, plus Medtronic's "conce[ssion] that the design . . . may not be modified without further FDA approval, unless the modifications do not affect the device's safety or effectiveness," *id.* at 228, support Petitioners' FCA allegations here. Those allegations – *i.e.*, that Medtronic made an undisclosed platinum sputter specification change, in violation of the FDA's Conditions of Approval and the Code of Federal Regulations, that Medtronic therefore sold a product that was different from the one the FDA had approved, and that Medtronic therefore caused the United States to pay over $500 million in false Medicare claims – were never made prior to Petitioners' *qui tam* complaint, and their merits have never been adjudicated.[5]

CONCLUSION

For the foregoing reasons, and for the reasons stated in the Petition, this Court should grant certiorari.

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[4] What the court found "specious" and "tenuous" (Opp. 3) was plaintiffs' legal argument that a specification for a different lead (the Model 4016A) became a specific federal requirement for the Model 4004M lead, because the Model 4016A was referenced in the Model 4004M application. 231 F.3d at 230-31.

[5] Medtronic has never asserted, nor has any court held, that there was prior "public disclosure" of Petitioners' *qui tam* claims in *Kemp*. That is because all of the platinum sputter-related allegations made in *Kemp* were made after Petitioners filed their April 1, 1998 *qui tam* complaint.

Respectfully Submitted,

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